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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,663	MILJKOVIC, DUSAN	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/5/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on June 16, 2008 with the cancellation of Claim 2.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3-20 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as presently claimed. Specifically, Claims 1 and 3-20, as amended, are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "sub-ripe, non-green dried *Coffea spec.* (coffee) cherry" in Claims 1, 3 , 15. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed on June 16, 2008 now either recite or depend from a claim that recites "A cosmetic composition comprising a composition prepared from a whole *Coffea spec.* (coffee) cherry, wherein the whole

Coffea spec. (coffee) used for the composition prepared from whole Coffea spec. (coffee) cherry is a sub-ripe, non-green dried *Coffea spec.* (coffee) that has a mycotoxin level of less than 20 ppb (part per billion) for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppm for total fumonisins"; or "A method of marketing a cosmetic composition comprising a step of providing the cosmetic composition and a further step of providing an information that the composition comprises a composition prepared from a whole *Coffea spec.* (coffee) cherry, wherein the whole *Coffea spec.* (coffee) cherry used for the composition prepared from the whole *Coffea spec.* (coffee) cherry is a sub-ripe, non-green, dried *Coffea spec.* (coffee) cherry) that has a mycotoxin level of less than 20 ppb (part per billion) for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppm for total fumonisins". However, the specification as originally filed provides only for compositions and/or methods for use thereof, wherein the composition is prepared from a whole *Coffea spec.* (coffee) cherry, which is sub-ripe and green or at least partially green. For instance, on page 3 of the specification, lines 29-30, Applicant discloses, "Viewed from an other perspective, sub-ripe cherries will typically exhibit at least some green color (at least 5%, more typically at least 10%) ...". On page 8 of the specification, line 24 bridging page 9, line 1, Applicant discloses under "*Harvest Of Whole Coffee Cherries*", "The ripeness of the coffee cherries was determined by visually estimating the amount 25 of green and red color (or yellow, where applicable) of the whole cherries. As the cherries ripen, the green cherries will typically increase in size and subsequently develop increasing amounts of red color. For the present examples, the coffee cherries were collected at four stages of ripeness:

Completely, or almost completely green (unripe; typically less than 5% of the coffee cherry red or yellow), primarily green with some red (semi-ripe, stage 1; typically less than 25% of the coffee cherry red or yellow), primarily red with some green (semi-ripe, stage 2; typically less than 25% of the coffee cherry green), and unbroken, unblemished red (almost ripe; typically less than 10% of the coffee cherry green; area of blemishes, cuts, or otherwise broken surface less than 5%)." Given the foregoing, it is readily clear that Applicant intended to direct the instantly claimed invention to a cosmetic composition comprising whole cherry Coffea sp., wherein the cherry is sub-ripe, green and dried and having a claim-designated mycotoxin level.

Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genera which would show possession of the concepts for a cosmetic composition comprising a composition prepared from a whole *Coffea spec.* (coffee) cherry, wherein the whole *Coffea spec.* (coffee) used for the composition prepared fro whole Coffea spec. (coffee) cherry is a sub-ripe, non-green dried *Coffea spec.* (coffee) that has a mycotoxin level of less than 20 ppb (part per billion) for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppm for total fumonisins or a method of marketing thereof, with regard to Claims 1, 3 and 15. There is only one exemplified composition/method, as set forth above. This is not sufficient support for the new aforementioned genera/genus. This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitation could not be found in the present specification, the recitation of the claim limitations is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 1 and 3-20, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied rejection as necessitated by amendment.

The metes and bounds of Claims 1, 3 and 15 are rendered vague and indefinite by the limitation, "a sub-ripe, non-green *Coffea spec.* (coffee) cherry because it is unclear as to the subject matter to which Applicant intends to seek patent protection because it is well known in the art of botany, as well as the coffee industry, that the term "coffee cherry" refers to the ripe, intact coffee fruit with (from outside in) skin, pulp, mucilage, parchment and bean (for example, see V2, http://www.coffee-ota-org/glossary.asp). Moreover, a green color is conventionally associated with immature coffee fruit, whereas a red color is generally associated with mature or ripen coffee fruit;

hence, the name "coffee cherry". For instance, on page 59, second paragraph, Clifford et al. teach (V1), "Coffee fruit develop during a period of some 35 weeks after the shrubs bloom, as illustrated in Figure 1 [citation omitted]. Maturity is indicated by the loss of chlorophyll from the pericarp and its replacement, by yellow flavone pigments in some cultivars, or more often by red flavonoid pigments [citations omitted]." Given, the foregoing the lack of clarity renders the claimed subject matter very confusing and ambiguous.

Claims 1 and 15 recite the limitation "the whole *Coffea spec.* (coffee) cherry used for the preparation prepared from whole *Coffea spec.* (coffee) cherry" in lines 2-3. There is a lack of clear insufficient antecedent basis for this limitation in the claims.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. In the instant case, Claim 7 fails to further limit the subject matter of a previous claim because it is not dependent upon any claim, yet not stand alone.

Claim 9 is objected to because of the following informality: There is an apparent omission of a verb in line 3 of the claim. Applicant may overcome the objection by adding is after "cherry". Newly applied as necessitated by amendment. Appropriate correction is required.

Claim 15 is objected to because of the following informality: There is an obvious misspelling in line 7. Applicant may overcome the objection by replacing "ppm" with ppb. Appropriate correction is required.

Applicant is advised that should Claim 19 be found allowable, Claim 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

Claims 1 and 3-5, 8-10 and 12-14, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sceopul (U or N) in view of Johnston et al. (A*), , Soucy (B*), Bucheli et al. (X2), Mann et al. (C*), Clifford (V1), Bertrand et al. (U2) and Suzuki (W2), and further in view of Batista et al. (W), Frank (W1), Helferich (W), Romani et al. (X), Codex Committee on Food Additives and Contaminants (X1 or CCFAC) and the United States Food and Drug Administration or USDA (U1). Newly applied as necessitated by amendment.

Applicant claims a cosmetic composition comprising a composition prepared from a whole *Coffea sp.* (coffee) cherry, wherein the whole *Coffea sp.* (coffee) cherry used for the composition prepared from whole *Coffea sp.* (coffee) cherry is a sub-ripe, non-green, dried *Coffea sp.* (coffee) cherry that has a mycotoxin level of less than 20 ppb (part-per-billion) for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppm for total fumonisins. Applicant further claims the cosmetic composition of claim 2 wherein the sub-ripe non-green *Coffea sp.* (coffee) coffee cherry is quick-dried such that a mycotoxin level of the *Coffea sp.* (coffee) cherry is less than 20 ppb (part-per-billion) for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppm for total fumonisins. Applicant further claims the cosmetic composition of claim 1 wherein the composition prepared from whole *Coffea sp.* (coffee) cherry preparation is a preparation from a quick-dried *Coffea sp.* (coffee) coffee cherry. Applicant further claims the cosmetic composition of claim 4 wherein the *Coffea sp.* (coffee) cherry is quick-dried such that a mycotoxin level of the *Coffea sp.* (coffee) cherry is less than 20 ppb (part-per-billion) for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppm for total fumonisins; wherein the composition prepared from whole *Coffea sp.* (coffee) coffee cherry preparation comprises at least two classes of compounds selected from the group consisting of coffee acids, coffee polyphenols, essential monosaccharides, coffee mucilage polysaccharides, and trigonelline, wherein the at least two classes of compounds are present in the extract in an amount of at least 1 wt% total. Applicant further claims the cosmetic composition of claim 8 wherein the at least two classes of compounds are present in the composition prepared from whole

Coffea sp. (coffee) coffee cherry is in an amount of at least 5 wt% total; and, wherein the coffee acids include a compound selected from the group consisting of chlorogenic acid, ferulic acid, and caffeic acid. Applicant further claims the cosmetic composition of claim 1 wherein the composition is formulated as one of a shampoo, a lotion, a cream, a balm, and an ointment; further comprising an information associated with the composition that the composition comprises the composition prepared from whole *Coffea sp.* (coffee) cherry; and, further comprising an information associated with the composition that the composition has an effect selected from the group consisting of an antioxidant effect, an anti-inflammatory effect, a UV (ultraviolet)-protective effect, an antimutagenic effect, a chemoprotective effect, a scar reducing effect, a skin-lightening effect, a moisturizing effect, a wrinkle reduction effect, and an antibacterial effect.

Sceopul teaches a cosmetic composition prepared from whole, sub-ripe coffee cherry, *i.e.*, the entire green fruit of coffee (*Coffea arabica*). See Column 1 of page 1, third paragraph to Column 2, line 7. Sceopul teaches, "Extracts of flowers and green fruit of the coffee plant obtained as follows: Flowers and fruit are washed with cold water and crushed in double cylinder extractors or electric grinders, giving creamy extracts varying in colour from yellow to grey-blue. Extract is purified and stabilizes with known preservatives and may be lyophilized to give fine stable powder." *See* abstract. As Sceopul teaches that whole, sub-ripe coffee cherry is used to prepare the extracts for cosmetic preparations, each of a bean of the coffee cherry, a pulp of the coffee cherry, a mucilage of a coffee cherry and a hull of the coffee cherry is inherent to the reference composition preparations. On page 1, second Column, line 36 to page 2, line 7,

Sceopul further teaches that the cherry coffee extracts comprise sugars (9.5%), caffeic acid, tannic acids (8.4%), *etc*. The extracts are used in the making of shampoo, lotion, cream, balm, and sunscreen. *See* page 1, Column 1, second paragraph; and examples. Sceopul also teaches that the extract comprises caffeic acid (a coffee acid) and cafetannic acid (a coffee polyphenol). The Sceopul' patent provides information associated with the compositions that the compositions protect the skin and hair from extraneous influences, and exhibit astringent, vasomotive, tonifiying effect on cutaneous tissue and moisturizing activity on skin and moisturizing and protective effect of keratin of the hair.

The teachings of Sceopul are set forth above. Sceopul teaches the instantly claimed cosmetic except for wherein the cosmetic composition is prepared from a sub-ripe, non-green dried whole coffee cherry which is quick-dried such that a mycotoxin level of the cherry is less than 20 ppb for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppm for total fumonisins. However, it would have been obvious to one of ordinary skill in the art to replace the green coffee cherry used in the making of the composition taught by Sceopul with the claim-designated ingredient to provide the instantly claimed invention because at the time the invention was made the following was well-known in the art of botany, mycology, and the coffee industry:

Firstly, prior studies showed that *Aspergillus, Penicillium* and *Fusarium* are natural coffee contaminants having the potential to produce aflatoxins, ochratoxins, and fumonisins which are detrimental to the quality and safety of the final product (*See* Batista, for instance, wherein Batista clearly teaches, "Like other crops, coffee cherries

and beans are subjected to contamination and consequent colonization by microorganisms during different phases of development, harvesting, transport and storage. Microbial action detrimental to the quality and safety of the final product will depend on environmental conditions as well as crop and product management. Studies on the microbiology of coffee cherries and beans have shown the main toxigenic fungal genera (*Aspergillus, Penicillium* and *Fusarium*) are natural coffee contaminants, and are present from the field to the warehouse", on page 293 bridging page 294, line 3 [citations omitted]. While the teachings of Frank are primarily concerned with the occurrence of ochratoxins in coffee processing from green coffee beans obtained from ripe cherries, Frank also teaches, "Lastly, a fresh cherry sample can be manipulated in the laboratory to assess the consequences of hypothetical circumstances such as a heavy superficial contamination of a particular fungus or removal of the natural external microbial flora", on page 6, third paragraph. Interestingly, Frank further teaches, "n) Outer fruit tissues more frequently contain *A. ochraceus* and OTA [ochratoxin] than beans but the concentration of the toxin is not always greater in these tissues than in the beans", on page 7. Of further interest is that Frank teaches that at harvest aspergilli, such as *A. ochraceus* are sometimes present but appear to be uncommon in coffee at harvest. Finally, Frank further teaches that growth of *A. ochraceus* (and other species with similar physiological properties) and OTA production is restricted to a fairly narrow window between A_w values of 0.94 and 0.80. Like Frank, Helferich teaches that aflatoxins are contaminants of agricultural crops, such as coffee. On page 108, second paragraph, Helferich teaches, "Aflatoxins have become generally accepted to be

poisonous and deleterious, and are now widely regulated in foods. In the U.S., the Food and Drug Administration (FDA) regulates feed and food containing aflatoxins at regulatory levels of 20 ppb of AFB_1 for human foods and selected animal feed". Helferich further teaches that ochratoxins are toxins found in coffee; and, that heat treatment at 250°C for 40 minutes provided a 76% reduction of the toxin in white flour. *See* page 108-109, under "*Ochratoxin A*". Furthermore, Romani teaches that international statutory limits for ochratoxin A (OTA) as regulated by Italy are 8 ppb for green coffee and 4 ppb for final product; 10 ppb as regulated by Finland; and 20 ppb as regulated by Greece. While the teachings of Codex Committee on Food Additives and Contaminants (CCFAC), with regard to fumonisins are predominantly directed to its occurrence in cereal grains, CCFAC teaches that *Fusarium* growth and mycotoxin production may continue to grown in agricultural crops if they are not sufficiently dried and that the when the content of small grain is reduced to approximately 15% growth of *Fusarium* species will stop. Furthermore, the FDA teaches, "The recommended maximum levels for fumonisins in corn and corn products intended for human consumption (Table 1) are based on concerns associated with hazards shown primarily by animal studies. However, based on available information on the occurrence of fumonisins, FDA believes that typical fumonisin levels found in corn and corn products intended for human consumption are much lower than the recommended level. For example, Table 1 indicates levels of 2-4 ppb of fumonisins in corn are acceptable levels for human consumption.

Secondly, each of Johnston, Mann and Soucy teaches quick-dry methods for reducing the number of toxigenic fungal genera and mycotoxin contaminants in whole coffee cherry or an agricultural crop of economic importance wherein mycotoxins may occur. For instance, Johnston teaches a method of preventing, eliminating or minimizing fermentation and enzymolysis caused by the action of microorganisms, including yeast, bacteria, and molds on whole coffee cherry by rapidly drying the whole cherry. *See* Column 1, lines 1-24; and, Column 2, lines 53-54. Next, Mann teaches a method for lowering the aflatoxin level in an agricultural product contaminated with aflatoxin by heat treatment for a period of time sufficient until the level of aflatoxin, as measured by chemical assay, ranges from about to 3 to about 14 ppb. In another example, Soucy teaches an process for drying whole coffee beans, coca beans (whole coffee cherry), and various grains; and, a method of use thereof. Soucy further teaches that the drying process is performed in an apparatus for the removal of moisture from bulk materials such as coffee cherry products which significantly reduces the moisture content. Finally, Bucheli demonstrates that reduction of ochratoxin in coffee plant materials of coffee cherry can be achieved by properly drying whole fruit of *Coffea sp.* under optimal conditions and within a short period of time after harvesting. Bucheli also teaches that the concentration of ochratoxins in coffee cherries is directly related to the coffee cherry maturity. For instance, Bucheli teaches that no evidence for the formation of ochratoxin is observed when unripe whole coffee cherries are dried within 1 to 5 days after harvesting. *See* Table 3 and Table 4.

Thirdly, Clifford reports the findings of a study assessing the change, with coffee fruit maturity, in the content of chlorogenic acids, caffeine and trigonelline in freeze-dried coffee beans of four different *Coffea sp*. As illustrated in Figures 2A-D, the most striking change for each type of bean was the pronounced sigmoidal increase in the total accumulation of caffeoylquinic acid in parallel with the total dry matter gain, and representing between 5% and 12% thereof, whereas there was a linear increase of caffeine and trigonelline on a mass per 100 bean basis. In another example, Bertrand teaches that the content of caffeoylquinic acid drastically increases at the end of the growth period of coffee fruits. Moreover, Suzuki shows that lower amounts of caffeine, theobromine and theophylline are present in the pericarp and seeds of immature green fruits of *Coffea arabica* with increasing amounts of the alkaloid compounds are observed in the plant materials as it ripens to a red color. The amounts of the compounds drastically decreased as the color changed to black in the latter stages of fruit maturation.

At the time the invention was made, one of ordinary skill in the art would have been motivated to replace the whole green coffee cherry used in the making of the composition taught by Sceopul with a sub-ripe, non-green, dried *Coffea sp*. (coffee) cherry that is quick-dried such that the mycotoxin level of the coffee cherry is less than 20 ppb (part-per-billion) for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppm for total fumonisins because the teachings of Clifford and Bertrand suggest that the content of coffee tannic acids in all portions of the whole coffee cherry is most pronounced at the end stage of fruit maturation; and, Clifford taught that coffee

fruit develops during a period of about 35 weeks after the shrubs blossom: "Maturity is indicated by the loss of chlorophyll from the pericarp and its replacement, by yellow flavone pigments in some cultivars, or more often by red flavonoid pigments [citations omitted]"; and, the teachings of Suzuki demonstrate that the amounts of alkaloids present in fruit plant material of coffee increase during the ripening of the fruit from green to red but rapidly decrease in concentration as coffee cherries overripe; and the teachings of Johnston, Soucy and Mann taught that quick-drying of whole coffee cherries or portions thereof or the quick-drying of agricultural crops susceptible to mycotoxin contaminations is useful in the drying of coffee plant materials and provide for a more microbially stabilized dried food product by reducing or killing bacteria and molds present on or in coffee plant parts, as well as inactivate or substantially reduce mycotoxins. Given the above combined teachings as a whole, the artisan of ordinary skill would have recognized that use of a sub-ripe, non-green whole coffee cherry or portion thereof as taught by Betrand, Clifford and Suzuki would have provided for the making of a cosmetic composition with increased amounts of caffetannic acids or alkaloids as taught by Sceopul to be therapeutic; and, one would have reasonably expected that the quick-drying process methods for drying or lowering the water activity or reducing the mycotoxin level of a coffee product or an agricultural crop as taught by Johnston, Soucy and Mann would be equally applicable to a whole coffee cherry that was not maturely ripe and non-green as taught to be successful in the quick-drying of coffee beans or other agricultural products by the references because it would have been no more than a matter of routine optimization to provide a result effect variable for

the reduction of microbial growth or mycotoxin by varying the experimental parameters known to be useful in controlling, preventing or minimizing the growth of mycotoxin-producing *Aspergillus, Penicillin* and *Fusarium* or inactivation of mycotoxins produced thereby, as taught by Helferich, Frank and the CCFAC; and, the experimental parameters for the drying of the coffee cherries used in the protocol of sample preparation as taught by Bucheli to assess ochratoxin production in cherries suggested that oven-drying at 70°C and/or freeze-drying of coffee cherries within a minimum time after fruit harvesting greatly reduces the production of ochratoxin and that accelerated drying of coffee cherries provides for a dried coffee cherry with either low detection or no detection of mycotoxins of varying ranges of ripeness or time of harvest; and, thereby one of ordinary skill in the art would have recognized that such a modification to the teachings of Sceopul' would be successful because it would address the concern of the international community for the occurrence of mycotoxins in products prepared from coffee cherry intended for human or animal consumption since it was known that aflatoxins, ochratoxins and fumonisins pose risk to the health of humans and animals and would meet the requirements for limited levels of mycotoxins in food crops as regulated by agencies such as the FDA. This reasonable expectation of success would motivate the skill artisan to modify the teachings of Sceopul to arrive at the instantly claimed composition.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of to the contrary.

Claims 1 and 3-5, 8-10 and 12-14, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sceopul (U or N) in view of Johnston et al. (A*), , Soucy (B*), Bucheli et al. (X2), Mann et al. (C*), Clifford (V1), Bertrand et al. (U2) and Suzuki (W2), and further in view of Batista et al. (W), Frank (W1), Helferich (W), Romani et al. (X), Codex Committee on Food Additives and Contaminants (X1 or CCFAC) and the United States Food and Drug Administration or USDA (U1); and further in view of The Free Dictionary by Farlex (U3). Newly applied as necessitated by amendment.

Applicant claims a method of marketing a cosmetic composition comprising a step of providing the cosmetic composition and a further step of providing an information that the composition comprises a composition prepared from a whole *Coffea spec.* (coffee) cherry, wherein the whole *Coffea spec.* (coffee) cherry used for the composition prepared from the whole *Coffea spec.* (coffee) cherry is a sub-ripe, non-green, dried *Coffea spec.* (coffee) cherry that has a mycotoxin level of less than 20 ppb (part-per-billion) for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppb for total fumonisins.

The obviated teachings of Sceopul in combination with the relied upon prior art references are set forth above. While the obviated teachings teach the instantly claimed composition and while the combined references disclose information associated with the obviated composition thereof, the combined teachings do not teach a method of marketing the instantly claimed composition. However, The Free Dictionary by Farlex the concept of marketing a product generally entails the following aspects:

> "The activities of a company associated with buying and selling a product or service. It includes advertising, selling and delivering products to people. People who work in marketing departments of companies try to get the attention of target audiences by using slogans, packaging design, celebrity endorsements and general media exposure. The four 'Ps' of marketing are product, place, price and promotion. Notes: Many people believe that marketing is just about advertising or sales. However, marketing is everything a company does to acquire customers and maintain a relationship with them. Even the small tasks like writing thank-you letters, playing golf with a prospective client, returning calls promptly and meeting with a past client for coffee can be thought of as marketing. The ultimate goal of marketing is to match a company's products and services to the people who need and want them, thereby ensure profitability".

Thus, given the teachings of the combined teachings as a whole, the instantly claimed method would have been *prima facie* obvious because a method of marketing a cosmetic composition wherein the information about the cosmetic product is printed on at least one of a container containing the formulation and a package containing the container would have been well within the purview of one ordinary skill in the art at the time the invention was made. One of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to augment the teachings of the combined references to provide the instantly claimed method of marketing a cosmetic prepared from a whole *Coffea spec.* (coffee) cherry, wherein the whole *Coffea spec.* (coffee) cherry used for the composition prepared from the whole *Coffea spec.* (coffee) cherry is a sub-ripe, non-green, dried *Coffea spec.* (coffee) cherry that has a mycotoxin level of less than 20 ppb (part-per-billion) for total aflatoxins, less than 10 ppb for total ochratoxins, and less than 5 ppb for total fumonisins, as taught by the obviated teachings set forth above, because the base teaching of Sceopul provides detailed

information heralding the beneficial functional activities of the product upon application, as well as all of the ingredients and amounts of ingredients used in the making of the reference formulations. Therefore, the instantly claimed method would have been no more than a matter of routine optimization to provide a result effect variable for the commercialization of the cosmetics taught by the combined teachings, especially since the information associated with such a composition would promote and emphasize the fact that it was low in mycotoxins; and, therefore non-toxic and fit for human and animal use. Furthermore, common sense would have dictated and rendered the claimed method of marketing *prima facie* obvious to one of ordinary skill in the art because at the time the invention was made it was old and conventional in the art of marketing a cosmetic, such as the skin and hair compositions taught by the primary reference of Sceopul, that the placement of printing or printed material on a container detailing information about the cosmetic, as well as on the packaging the container, was beneficial in providing a vehicle for containing the product and a viable means for the mass distribution, delivery and storage of the product wherein the printed information on the container provides a means for the identification, promotion and sale of a product to a consumer base in want or need of a cosmetic product having beneficial functional effects.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1 and 3-6 and 8-14, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Sceopul (U or N) in view of Johnston et al. (A*), , Soucy (B*), Bucheli et al. (X2), Mann et al. (C*), Clifford (V1), Bertrand et al. (U2) and Suzuki (W2), and further in view of Batista et al. (W), Frank (W1), Helferich (W), Romani et al. (X), Codex Committee on Food Additives and Contaminants (X1 or CCFAC) and the United States Food and Drug Administration or USDA (U1); and further in view of Fischer et al. (V3), Clifford et al. (W3) and Coleman et al. (X3), and further in view of Pineau et al. (E*), Huang et al. (U4) and Stuckler et al. (O). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 1, 3-5, 8-10, and 12-14 was set forth above. Applicant further claims the cosmetic composition of claim 1 wherein the *Coffea spec.* (coffee) cherry preparation comprises at least one of an aqueous extract and an alcoholic extract. Applicant further claims the composition of claim 8 wherein the class of essential monosaccharides includes a compound selected from the group consisting of arabinose, fucose, mannose, xylose and galactose.

The obviated teachings of Sceopul in combination with the relied upon prior art references are set forth above. The combined references teach the instantly claimed composition except for wherein the *Coffea spec.* (coffee) cherry preparation comprises at least one of an aqueous extract and an alcoholic extract; and, wherein the class of essential monosaccharides includes a compound selected from the group consisting of arabinose, fucose, mannose, xylose and galactose.

Fischer teaches an alcohol extract of green beans of *Coffea Arabica* comprise fucose, rhamnose, arabinose, galactose, glucose, xylose, and mannose (55.8%) in Table 1; Clifford teaches extraction of chlorogenic acids, caffeine and trigonelline from dried green coffee beans (*Coffea arabica*) with water; and, Coleman teaches extraction of crude coffee cherry mucilage with ethanol to obtain a galacturonic acid fraction comprising arabinose, galactose, xylose and rhamnose. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation to optimize the composition taught by the obviated teachings of Sceopul by employing at least one of an aqueous solvent and an alcohol solvent to provide the instantly claimed composition because at the time the invention was made it was known that the claim-designated solvents were useful in the extraction of beneficial compounds having health promoting effects on the skin and hair, as evidenced by the teachings of Pineau and Huang. For instance, Pineau taught that the application to skin cosmetic compositions comprising at least one polyholoside comprising at least two monosaccharides, such as arabinose, xylose, fucose, mannose, galactose for promoting desquamation of the skin of a mammalian organism in need of such treatment and/or to stimulate epidermal renewal and/or inhibit intrinsic and/or extrinsic cutaneous aging; Huang taught that topical skin compositions comprising chlorogenic acid, caffeic acid and ferulic acid exert inhibitory effect on tumor promotion in mouse skin by 12-O-tetradecanoyolphorbol-13-acetate; Stuckler taught that trigonelline is useful in the making of cosmetic compositions for topical administration, e.g., as lotions or shampoos, for nail, skin and hair care, for reducing hair loss and for

stimulating hair growth; and, Bucheli suggested that the sugar content of a coffee cherry is dependent upon its maturity with unripe coffee cherries showing glucose and fructose concentrations much lower than ripe coffee cherries, which would have provided the artisan of ordinary skill to select a sub-ripe non-green coffee cherry with a reasonable expectation of success for providing to arrive at the instantly claimed cosmetic composition.

Thus, the instantly claimed extract would have been *prima facie* obvious and no more than a matter of optimization to provide a result effect variable to one of ordinary skill in the art practicing the invention at the time the invention was made, given that the references before him or her taught that the claim-designated plant materials and claim-designated solvents were useful in the extraction of classes of compounds from a coffee cherry known in the art to have health promoting effects and could be used in the making of cosmetic compositions having antioxidant effect, anti-inflammatory effect, ultraviolet protective effect, chemoprotective effect, scar reducing effect, moisturizing effect, and wrinkle reduction effect.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
September 2, 2008

/Michele Flood/

Primary Examiner, Art Unit 1655